

SEP - 6 1996

510K SUMMARY

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IGENICS, INC.
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Contact Person: Eduard T. van Breen, President

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Trade name of Device: None (to be produced for multiple private labels)
Common Name: Drain/Slit Sponge (Non-Sterile and Sterile)
Classification Name: Synthetic Sponge (Non-Sterile and Sterile) (21 CFR 878.4060)

The products to be manufactured by Igenics, Inc. are non-sterile and sterile versions of a nonwoven synthetic drain/slit sponge that is substantially equivalent to the general use sponges currently produced by Igenics, Inc. for multiple private labels. For other substantially equivalent devices, see general use sponges marketed by Johnson & Johnson Medical, Inc. known as Nu Gauze and general use sponges marketed by Kendall Co. known as Versalon. The drain/slit sponges do not have a different intended use or different technological characteristics than the general use sponges, except that the drain/slit sponges have a slit cut in them to accommodate a tube or needle. The drain/slit sponges are made of rayon and polyester fibers and will be sterilized by radiation or ethylene oxide methods. The finished products have a pattern similar to traditional cotton gauze, but they are softer and more absorbent. The Igenics products also have minimal linting and wound adhesion compared to traditional cotton gauze. It is intended that the drain/slit sponges will be used as a dressing around tubes and needles and for other general medical and dental purposes for which cotton gauze has traditionally been used.